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Korean American Women: A Randomized Controlled Trial

PRINCIPAL INVESTIGATOR: Annette Maxwell, Ph.D.

CONTRACTING ORGANIZATION: University of California

Los Angeles, CA 90095

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assessment and 72 women received the peer navigator intervention. Result: Based on intent-to-treat analysis of all women who were randomized with imputation of no completion of follow-up exam for women who refused participation, could never be contacted or dropped out, self-reported completion of follow-up was 61% in the intervention arm and 46% in the control arm (p<.055). Less conservative analyses suggest that the intervention was efficacious.

#### 15. SUBJECT TERMS

Completion of diagnostic follow-up tests after breast abnormalities; low-income Korean Women; randomized controlled trial; peer navigator intervention

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# **Table of Contents**

	Page
Introduction1	
Body2	
Key Research Accomplishments5	
Reportable Outcomes6	
Conclusion6	
References7	•
Appendices9	)

Award: DAMD17-03-1-0676 Author: Annette E. Maxwell, Dr.P.H.

#### **INTRODUCTION:**

Experience shows that a substantial proportion, as much as 15-20% of women who receive a screening mammogram and/or a clinical breast exam, require follow-up diagnostics and/or treatment (Lerman et al., 1991, Winchester et al., 1988). Timely follow-up of abnormalities is essential because delays may lead to postponement of treatment and decreased survival for women who have cancer. The 5 year survival rate for localized breast cancer is 98%, but this rate drops substantially if breast cancer is diagnosed at a regional or distant stage (84% and 27% respectively; ACS 2008).

Incomplete follow-up of potential breast problems ranges from 18% to 80% (McCarthy et al., 1996a, Mandelblatt et al., 1996, Peek and Han 2009), using different definitions and different health care settings. Factors associated with incomplete and delayed follow-up of abnormal cancer screening tests are older age, low income and education level, nonwhite race, less social support, patients' lack of remembering a specific follow-up recommendation, concerns about medical care cost, lost wages and transportation, and patients' fears (Burack et al., 2000, Rojas et al., 1996; McCarthy et al., 1996a,b; Michielutte et al., 1985; Chang et al., 1996; Crane 1996, Press et al., 2008, review article by Wujcik and Fair 2008). Facione and colleagues (2000) conducted focus groups with Chinese American immigrants and found some culturally specific beliefs and attitudes, including a sense of invulnerability to breast cancer, a linking of cancer to tragic luck, the tendency to delay action, and the tendency to favor Chinese medicine and delay Western therapies to preserve modesty and to conserve wealth and time. These findings suggest that, especially among first generation Asian Americans, language barriers, an unfamiliarity with the local health care system and with western medicine in general, and cultural beliefs and values may negatively affect adherence to follow-up procedures.

Based on a review of the breast and cervical cancer literature, strategies to increase adherence to diagnostic follow-up include **educational interventions** such as mail and telephone delivery of educational brochures and scripted materials (Marcus et al., 1998, Paskett et al., 1995, 1998; Stewart et al., 1993, 1994); **behavioral interventions** such as mail and telephone confirmation/reminders (Miller et al., 1997, Del Mar et al., 1995), economic vouchers/transportation incentives (Marcus et al., 1992, 1998), pre-appointment telephone barriers counseling (Miller et al., 1997); and **clinic based interventions** such as computer tracking system, educational intervention for providers, and a clinic-based case management protocol (Paskett et al., 1998). Several studies have reported improved adherence to follow-up procedures among minority women who received assistance through a patient navigator, a trained woman, usually from the same cultural background as the patients, that accompanies the patient to follow-up appointments, and provides emotional support and advocacy (Burhansstipanov et al., 1998, Battaglia et al., 2006, Palmieri et al., 2009, Crump et al., 2008, Ell et al., 2007, Ferante et al., 2008).

The purpose of this study was to design and test an intervention to assist Korean American women who have been identified with a potential breast abnormality through the Breast Cancer Early Detection Program (BCEDP) and who have missed their first follow-up appointment (at-risk women). The intervention took place in the form of peer navigation which included reminder phone calls, emotional support, help with transportation to follow-up appointments, translations, and other assistance to overcome barriers to completing follow-up diagnostic procedures.

#### **BODY:**

Following activities as listed in the Statement of Work have been completed:

## Task 1: Setup and Formative Research

After receipt of the DOD Human Subject approval in August 2005, we hired and trained 3 mature, English-Korean bilingual bicultural Korean American peer navigators. They received training on research ethics, the study protocol, interviewing techniques, and clinic policies and procedures pertaining to BCEDP. During the initial months (August – October) one navigator was assigned to each of the three clinics. However, we realized that the workload per navigator was often less than 20% per given week. As a result, two of the navigators left our study to find work with longer hours. Also during this time, one of the clinics withdrew from participation. Due to financial constraints, this clinic was experiencing an agency-wide restructuring which resulting in staffing problems unrelated to this study. Although both partners had agreed on the scope of work and on the budget, the study became a burden to this clinic. Thus, we decided to have the remaining navigator cover both of the remaining clinics.

The study was conducted at a community clinic and a private practice. Both sites provide free screening mammograms to Korean American women for the Breast Cancer Early Detection Program. We conducted exploratory one-to-one interviews with health care providers who serve Korean American women with abnormal mammograms and with Korean American women who have been referred for follow-up diagnostics. Health care providers stated that Korean American women who need a follow-up procedure face language barriers, lack transportation, do not understand the importance of follow-up and the fact that procedures are paid through the Cancer Detection Program, and have the fear of getting lost and being helpless at an unfamiliar and large health care facility. Both providers and KA women stated that a peer navigator could help women in overcoming these barriers to diagnostic follow-up and also serve as an advocate in the community to raise awareness and adherence. Based on these findings, we designed an intervention that utilized a peer navigator model. Dr. Jo, Co-investigator, conducted the training of the peer navigators, and worked closely with the peer navigator in identifying women at risk, in randomizing women, and in monitoring her interactions with participating women on a weekly basis. All intervention activities and assessments were conducted in Korean language, which was the preferred language for all participants.

Randomization: We used a random number table to randomly assign subjects into control or intervention arm. Each women who is identified by the BCEDP case manager through BCEDP records is given an ID number. We randomized women with an odd ID number to the intervention arm, and those with an even ID number to the control arm.

*Intervention:* An English-Korean bilingual Korean American patient navigator was trained to provide individually tailored assistance to the women in our intervention arm, including reminding women before an appointment, explaining the need for and the nature of the diagnostic follow-up exam, meeting women at the referral clinic, helping them to complete forms, providing information and emotional support. Based on the Health Behavior Framework (Bastani et al., 2009), the intervention was designed to increase knowledge and self-efficacy among women to complete the exam, and to assist women in overcoming barriers to completing the exam. The patient navigator was selected based on her ability to assist women to navigate the medical system and her ability to advocate for timely completion of the follow-up.

Training of peer navigator: Training took place over the course of three half days, and covered the following topics: breast health and cancer, focusing on prevention and early detection methods, screening abnormalities and follow-up diagnostics; pertinent key medical terms and concepts; BCEDP program and its protocols; study protocol and forms involved with the study; information about the medical facilities involved, including information about the two study clinics and the typical referral centers; types of assistance to be offered to the women; and general etiquettes and safety precautions in working with strangers. The patient navigator was also given written materials and other resources from the American Cancer Society, the Komen Foundation, and the National Cancer Institute (i.e., videotapes, websites). Additionally, prior to any human subjects contact, she received IRB and HIPAA compliance trainings

*Pretesting:* During the month of August, we pretested the intervention in 8 Korean American women. We paid special attention to the order and flow of the questionnaire and the content of the intervention. Survey questionnaire and the content of the intervention did not require changes but we modified the log forms that were used by the navigators to keep track of their activities and subject's needs and activities.

*Human Subject Approvals:* The study was approved by the Institutional Review Board of the University of California, Los Angeles and the Army Surgeon General's Human Subjects Research Review Board (HSRRB; HRPO Log No. A-12113.0).

## Task 2: Enrolling Subjects into Randomized Trial

Study Design: Eligible subjects were randomly allocated to be enrolled in an intervention or a usual care arm of the study (see Figure 1). Usual care arm: Women received usual care according to the BCEDP protocol, consisting of up to 2 telephone calls by the BCEDP case manager and, if needed, a registered letter, urging them to make an appointment for a follow-up exam. Intervention arm: Women were called within 5 days of their missed appointment and invited to participate in a study in which a Korean American peer navigator would assist them in obtaining their follow-up exam. Women who provided oral consent received a peer navigator intervention in addition to usual care provided by the BCEDP program. Six months after random allocation, all women were invited to participate in a telephone survey that was conducted in Korean language. This was the first study contact for women in the usual care arm and the interviewer obtained verbal consent from them prior to the interview. Therefore, the interviewer was aware of subjects' group status. Women in both arms of the study were also asked for permission to conduct a chart review to verify that all follow-up exams had been completed (see study design in Figure 1). Women who consented to this part of the study signed a HIPPAA form.

Between August 2005 and December 2007, we identified 176 eligible women from the BCEDP logs at the two participating clinics. This number does not include 15 women who became eligible 6 months prior to the beginning of the prospective study, which were included in our counts in previous progress reports. We allocated 92 women to the prospective intervention arm and 84 women to the retrospective usual care control arm of the study. We obtained consent to participate from 79/92 women in the prospective intervention arm (86%) and from 58/85 women in the retrospective usual care control arm (69%). The reason for the lower participation rate in the control arm is that women were contacted 6 months after identification and a large number was unreachable at that time (14/84 = 17%). In comparison, in the intervention arm, in which women were contacted within 5 days after identification, only 5/92 = 5% were unreachable.

## **Task 3: Conducting Intervention**

Each woman in the intervention arm who consented to participate (N=79) was contacted through telephone or in-person by our peer navigator for an initial needs assessment. We were successful in contacting the majority of our subjects through telephone. Initial contacts were made through telephone using the numbers given to us by the participating clinics. If we were not successful with the telephone numbers (i.e. disconnected or no longer residing at such location), we contacted the clinic for accuracy of numbers and obtained any other alternate numbers. We mailed a questionnaire to women that we were not able to reach by phone. However, none of the women responded to the mailed questionnaire. Next, our peer navigator followed up with each patient to address their identified need (i.e. reminder call prior to appointment, provide transportation, provide translation, fill out paper work at the hospital, provide emotional support, answer questions, etc.). A total of 72 out of 79 women have received the peer navigator intervention.

The peer navigator provided the following services (number of women in parentheses): answered questions (69), made reminder calls (64), provided reassurance (57), provided in-person help at the hospital (54), provided translation services (52), filled out forms (49), rescheduled appointment for follow-up test (42), gave directions to the hospital (23), provided transportation (2), made a home visit (1), provided other services (10). On average, the peer navigator provided  $5.4 \pm 2.6$  services per woman and the average number of contacts per woman was 3.8 + 1.7.

Many of the women in the control condition eventually complete their follow-up of abnormalities. For those that did not complete their follow-up, we offered the identical intervention after completion of the 6 month follow-up survey. Of the 58 women in the control arm who have completed the survey, 39 have completed their follow-up of abnormalities based on self-report. We offered help to the 19 women in the control arm who did not complete follow-up. Only two women agreed to receive help and completed their follow-up with the help of the peer navigator.

#### **Task 4: Collecting Data**

The patient navigator completed an <u>intake form</u> during her first telephone contact or face-to-face meeting with women assigned to the intervention arm that allowed her to tailor her assistance to each woman's individual needs. In a <u>log sheet</u>, she noted all contacts and the type of assistance that she provided to each woman. A <u>telephone survey</u> was administered to 116 women in both study arms 6 months after they were identified to assess demographic and socio-economic characteristics including various measures of acculturation, health insurance status, perceived health status, type of abnormality and recommended follow-up exams and the outcome of interest: self-reported completion of the recommended follow-up exam. Most of the interviews were conducted by the Co-investigator, Dr. Jo, who had not been in contact with the subjects during the intervention activities, to reduce social desirability bias. <u>Chart reviews</u> were conducted for a total of 47 women who provided written consent for this part of the study. We were not able to conduct chart reviews for all subjects since most women in the control arm did not give consent to this activity. This may be due to the fact that we don't have face to face contact with women in the control arm. Therefore, we will not be able to report the outcome based on chart reviews, but have to rely on self-report instead. We completed chart reviews for 47 women who gave permission (40 in the intervention arm and 7 in the control arm).

## Task 5: Data Management and Analysis

All data have been entered, cleaned and analyzed. We are currently in the process of completing a manuscript describing findings of the study.

#### **KEY RESEARCH ACCOMPLISHMENTS:**

Because women in the usual care control arm of the study only completed one telephone survey 6 months after the potential abnormality was identified, we are reporting sample characteristics for both groups based on this survey. Study participants were, on average, 52 years old. They were all foreign-born and had lived in the United States for an average of 17 years (see Table 1). About three-quarters were married and 80% reported an annual household income less than \$30,000. Most considered themselves more Korean than American (87%) and the vast majority used Korean language with their friends, watched Korean TV and read Korean newspapers. Only 16% had health insurance. (Only low-income women without or with insufficient health insurance qualify for the BCEDP program). No statistically significant differences between study arms were found in any demographic variables that were assessed.

Only 10% of the women described their health status as excellent or very good, followed by good (24%), fair (45%) and poor (21%). Most women in our sample had an abnormal or suboptimal mammogram (71%) or an abnormal clinical breast exam (15%), and had a referral for a diagnostic mammogram with or without ultrasound (89%). This required a referral to a larger clinic, because both recruitment clinics only offered screening mammograms (2 views) and were not equipped to perform diagnostic mammograms. Only one woman was referred for an ultrasound guided core biopsy. Most women stated that they were somewhat (63%) or very comfortable (31%) discussing health care with a provider. While most women stated that they were not at all or a little worried when they received the referral for a follow-up exam 6 months ago (60%), a substantial minority was quite a bit or very much worried (40%). No statistically significant differences between study arms were found in any health related variables that were assessed (see Table 2).

The intake form that the peer navigator administered to women assigned to the intervention arm revealed that most women obtained their mammogram during which the potential abnormality was identified based on a doctor's recommendation or as part of their yearly routine screening. However, a substantial proportion stated that they obtained the exam because they felt a lump (38%) or because of pain or nipple discharge (17%). Although most were treated politely at their last clinic visit and had their questions answered, large proportions stated that they had problems communicating with the doctor or the staff (74%), that they found it difficult to ask questions (45%) and that they had to wait too long to be seen (33%). Although the diagnostic follow-up exam is covered by the BCEDP program, more than 90% of the women were concerned about the cost of the recommended exam, and about 70% were worried about the recommended follow-up exam or treatment and about the possibility that the exam may find a serious problem. About three-quarters of the women stated that they wanted to receive a reminder about their follow-up appointment and one quarter wanted more information about the recommended exam (see Table 3).

Based on intent-to-treat analysis of all women who were randomized with imputation of no completion of follow-up exam for women who refused participation, could never be contacted or dropped out, self-reported completion of follow-up was 61% in the intervention arm and 46% in the control arm (p<.055, **Table 4**). A less conservative computation that only included study completers yielded completion rates of 97% in the intervention arm and 67% in the usual care control arm (p<.001). It is probably too conservative to assume that

all women who did not complete the survey did not complete their follow-up diagnostic exam. Therefore, the true proportion may lie somewhere inbetween the estimates derived from the two analysis approaches. If we assume that at least 5% of women who did not complete the follow-up survey completed diagnostic follow-up procedures in both arm of the study, the difference in completion of follow-up procedures is statistically significant at p<.05.

Of the 40 charts reviewed for women in the intervention group, all confirmed self-reported completion of the follow-up exam. In the control group, 5 out of 7 charts confirmed self-reported completion. While this number is not sufficient to conduct sensitivity and specificity analysis, these results suggest that self-report is a valid outcome measure.

#### **REPORTABLE OUTCOMES:**

In addition to an early presentation that introduced the study in 2005 and a 2007 presentation, we provided preliminary results at the 2008 DOD Era of Hope Conference.

Maxwell AE, Jo A, Bastani R. Increasing adherence to follow-up of breast abnormalities in low-income Korean American women. Era of Hope Department of Defense Breast Cancer Research Program meeting, Philadelphia, Pennsylvania, June 8-11, 2005.

Jo AM, Maxwell AE, Thai L, Kim MJ, Bastani R. Assisting Korean American women with follow-up of breast abnormalities. 23rd Annual UCLA Multi-Campus Family Medicine Research Forum. Northridge Hospital Medical Center. May 8, 2007 (Best Poster Award).

Maxwell AE, Jo AM, Bastani R. Peer navigation improves adherence to follow-up diagnostics among Korean American women with suspected breast abnormalities. Abstract #P7-1. Era of Hope Meeting, Department of Defense Breast Cancer Research Program, Baltimore, Maryland, June 25-28, 2008.

#### **CONCLUSION:**

The peer navigator intervention is well accepted and appreciated by the women and the participating clinics. Completion rates of diagnostic follow-up procedures are higher than we had expected in this group of women who had already missed their first follow-up appointment. The majority of women in the control group report that they completed all follow-up procedures without assistance. However, completion rates are substantially higher in the intervention group. These results suggest that a peer navigator intervention to assist Korean American women to obtain follow-up diagnostic tests after an abnormal mammogram is efficacious in this population.

#### **REFERENCES:**

American Cancer Society. Cancer Facts & Figures 2008. Atlanta: American Cancer Society; 2008.

Bastani R, Glenn BA, Taylor VM, Chen MS Jr, Nguyen TT, Stewart SL, Maxwell AE. Integrating theory into community interventions to reduce liver cancer disparities: The Health Behavior Framework. *Preventive Medicine*, in press 2009.

Battaglia TA, Roloff K, Posner MA, Freund KM. Improving follow-up to abnormal breast cancer screening in an urban population. A patient navigation intervention. Cancer 15:1092 (2 Suppl):359-67, 2007.

Burack RC, Simon MS, Stano M, George J, Coombs J. Follow-up among women with an abnormal mammogram in an HMO: is it complete, timely, and efficient? American Journal of Managed Care 6:1102-13, 2000.

Burhansstipanov L, Wound DB, Capelouto N, Goldfarb F, Harjo L, Hatathlie L, Vigil G, White M. Culturally relevant "Navigator" patient support. Cancer Practice 6(3):191-4, 1998.

Chang SW, Kerlikowske K, Napoles-Springer A, Posner SF, Sickles EA, Perez-Stable EJ. Racial differences in timeliness of follow-up after abnormal screening mammography. Cancer 78:1395-402, 1996.

Crane LA. Social support and adherence behavior among women with abnormal pap smears. J Cancer Educ 11:164-73, 1996.

Crump SR, Shipp MP, McCray GG, Morris SJ, Okoli JA, Caplan lS, Thorne SL, Blumenthal DS. Abnormal mammogram follow-up: Do community lay health advocates make a difference? Health Promotion Practice 9(2): 140-148, 2008.

Del Mar CB, Wright RG. Notifying Women of the Results of their Cervical Smear Tests by Mail: Does it Result in a Decreased Loss to Follow-Up Abnormal Smears? Aust Journal of Public Health 19:211-3, 1995.

Facione NC, Giancarlo C, Chan L. Perceived risk and help-seeking behavior for breast cancer. A Chinese-American Perspective. Cancer Nursing 23:258-267, 2000.

Ell K, Vourlekis B, Lee PJ, Xie B. Patient navigation and case management following an abnormal mammogram: a randomized clinical trial. Prev Med 44:26-33, 2007.

Ferante JM, Chen P, Kim S. The effect of patient navigation on time to diagnosis, anxiety, and satisfaction in urban minority women with abnormal mammograms: A randomized controlled trial. Journal of Urban Health 85(1):114-124, 2008.

Lerman C, Trock B, Rimer BK, Boyce A, Jepson C, Engstrom PF. Psychological and behavioral implications of abnormal mammograms. Ann Intern Med 114:657-661, 1991.

Mandelblatt J, Freeman H, Winczewski D, Cagney K, Williams S, Trowers R, Tang J, Kerner J. Implementation of a breast and cervical cancer screening program in a public hospital emergency deparatment. Cancer Control Center of Harlem. Annals of Emergency Medicine 28:493-8, 1996.

Marcus AC, Crane LA, Kaplan CP, Reading AE, Savage E, Gunning J, Bernstein G, Berek JS. Improving adherence to screening follow-up among women with abnormal pap smears: results from a large clinic-based trial of three intervention strategies. Medical Care 30:216-30, 1992.

Marcus AC, Kaplan CP, Crane LA, Berek JS, Berstein G, Gunning JE, Mc Clatchey MW. Reducing loss-to-follow-up among women with abnormal smears. Results from a randomized trial testing an intensive follow-up protocol and economic incentives. Medical Care 36:397-410, 1998.

McCarthy BD, Yood MU, Boohaker EA, Ward RE, Rebner M, Johnson CC. Inadequate follow-up of abnormal mammograms. American Journal of Preventive Medicine 12:282-8, 1996a.

McCarthy BD, Yood MU, Janz NK, Boohaker EA, Ward RE, Johnson CC. Evaluation of factors potentially associated with inadequate follow-up of mammographic abnormalities. Cancer 77:2070-6, 1996b.

Michielutte R, Diseker RA, Young LD, May WJ. Noncompliance in screening follow-up among family planning clinic cervical dysplasia. Prev Med 14:248-58, 1985.

Miller SM, Siejak KK, Schroeder CM, Lerman C, Hernandez C, Helm W. Enhancing adherence following abnormal pap smears among low-income minority women: a preventive telephone counseling strategy. Journal of the National Cancer Institute 89(10):703-8, 1997

Palmieri FM, DePeri ER, Mincey BA, Smith JA, Wen LK, Chewar DM, Abaya R, Colon-Otero G, Perez EA. Comprehensive diagnostic program for medically underserved women with abnormal breast screening evaluation in an urban population. Mayo Clin Proc 84:317-322, 2009.

Paskett ED, Phillips KC, Miller ME. Improving compliance among women with abnormal Papanicolaou smears. Obstet. Gynecol 86:353-9, 1995.

Peek ME and Han JH. Compliance and self-reported barriers to follow-up of abnormal screening mammograms among women utilizing a county mobile mammography van. Health Care Women Int 30:857-70, 2009.

Press R, Carrassquillo O, Sciacca RR, Giardina EG. Racial/ethnic disparities in time to follow-up after an abnormal mammogram. J Womens Health (Larchmt) 17:923-30, 2008.

Rojas M, Mandelblatt J, Cagney K, Kerner J, Freeman H. Barriers to follow-up of abnormal screening mammograms among low-income minority women. Cancer Control Center of Harlem. Ethnicity and Health 1:221-8, 1996.

Stewart DE, Lickrish GM, Sierra S, Parkin H. The effect of educational brochures on knowledge and emotional distress in women with abnormal Papanicolaou smears. Obstet Gynecol 81: 280-282, 1993.

Stewart DE, Buchegger PM, Lickrish GM, Sierra S. The effect of educational brochures on follow-up compliance in women with abnormal Papanicolaou smears. Obstet Gynecol 83:583-4, 1994.

Winchester DP, Lasky HJ, Sylvester J, Maher ML. A television-promoted mammography screening pilot project in the Chicago metropolitan area. CA 38:291-309, 1988.

Wujcik D and Fair AM. Barriers to diagnostic resolution after abnormal mammography: a review of the literature. Cancer Nurs 31(5):E16-30, 2008

## **APPENDICES:**

- 1. Revised Statement of Work
- 2. Study Flow chart and tables 1-4

## **Statement of Work** (Revised August 20, 2008)

Note: Because it took almost two years to obtain Human Subject approval for tasks 2 to 5 (see Table 1), this revised SOW shows the planned and the actual time line.

Table 1: Project Timeline and Human Subject Approvals

Time period	Months of Timeline	DOD Human Subject approvals
Sep 03 – Aug 04	01 - 12	
Sep 04 – Aug 05	13 - 24	12/04 approval for task 1; 8/05 approval for tasks 2 - 5
Sep 05 – Aug 06	25 - 36	
Sep 06 – Aug 07	37 - 48	
Sep 07 – Aug 08	49 - 60	
Sep 08 – Aug 09	61 - 72	

## Task 1: Setup and Formative Research (planned: Months 01-06; actual: Months 17-22)

- a. Develop discussion guides for semi-structured interviews (English and Korean, using standard translation procedures including back translations)
- b. Identify women who received a referral for follow-up procedures in the past 12 months from BCEDP logs. Conduct telephone interviews (N=20) with these women (Angela Jo, Kim Young)
- c. Identify 5 health care professionals through participating sites and conduct semi-structured interviews (Maxwell, Jo, Young)
- d. Draft intervention components (strategies, scripts, materials) and assessment forms (intervention activity logs, needs assessment questions) all materials in English and Korean language
- e. Hire and train 3 mature, English-Korean bilingual Korean American peer counselors
- f. Establish procedures to identify women who missed follow-up appointments on a daily basis
- g. Pretest intervention in 6-10 KA women, revise and finalize
- h. Establish randomization procedure

## Task 2: Enroll subjects into randomized trial (planned: Months 07-30; actual: Months 25-54)

a. Identify eligible subjects (N=253 during the 2 year recruitment), randomize into the study and administer verbal informed consent to intervention subjects (choice of English or Korean).

## Task 3: Conduct Intervention (planned: Months 07-33; actual: Months 25 - 60)

- a. Conduct telephone needs assessment and counseling for each newly enrolled intervention subject (N=86). Contact each intervention subject at least once every other week until completion of diagnostic follow-up/treatment. Offer intervention components as appropriate.
  - b. Document all contacts, responses to needs assessment questions, intervention requests and activities.
  - c. Conduct alternative protocol for intervention subjects who cannot be reached by telephone.
  - d. After completion of the follow-up survey, provide intervention to women in the control group

who did not complete follow-up procedures.

## Task 4: Data Collection (planned: Months 3-40; actual: Months 25 - 70)

- a. Collect and compile log sheets from contacts with intervention subjects (process measures) into a data base (months 7-35)
- b. Develop (draft, translate, back translate, pretest, revise) follow-up survey based on the Adherence Model (months 3-12)
- c. Hire and train interviewer(s) to conduct follow-up survey (months 12-13)
- d. Conduct post-intervention survey with all subjects (N=160) 6 months after referral for diagnostic follow-up. Administer verbal consent prior to conducting survey to subjects in the control group (months 13-40)
- e. Conduct chart reviews for all subjects (N=160) 6 months after referral for diagnostic follow-up (months 13-40)

# Task 5: Data Management and Analysis (planned: Months 1-42; actual: Months 17 - 72)

- a. Transcribe and translate into English audiotapes from semi-structured interviews.
- b. Analyze qualitative and quantitative data from Task 1.
  - For qualitative data analysis, summarize transcripts from semi-structured interviews, including key points and notable quotes (in English and Korean language) using standard procedures (Krueger 1994); compare and consolidate summaries prepared independently by two Korean speaking investigators (Drs. Jo and Kim); sort findings by the domains of the Adherence Model.
  - For quantitative analysis, tabulate findings from semi-structured interviews, including specific needs expressed, services requested and barriers and concerns voiced about follow-up procedures. Tabulate findings from chart reviews by adherence status.
- c. Set up data entry programs and enter information from intervention log sheets, needs assessments, intervention requests and activities (process measures)
- d. Set up data entry program and enter information from 6 month follow-up survey
- e. Set up data entry program and enter information from chart reviews
- f. Data management and cleaning will be ongoing
- g. Data analysis, preparation of annual reports and manuscripts.

Table 1. Sample Characteristics by Study Group

	Intervention (n=58)		Control (n=58)		Total (n=116)		
	n	%	n	%	n `	%	p-value <sup>a</sup>
Age in Years (52 ±8, 40-73)*							
40 to 49	24	41	17	35	41	39	0.794
50 to 59	22	38	21	44	43	41	
60 or older	12	21	10	21	22	21	
Marital Status							
Married	41	77	39	75	80	76	0.777
Not Married	12	23	13	25	25	24	
Annual Household Income							
< \$10,000	12	25	13	28	25	26	0.265
\$10,000 to < \$20,000	13	27	17	36	30	32	
\$20,000 to < \$30,000	14	29	6	13	20	21	
\$30,000 or more	9	19	11	23	20	21	
Education							
< High School	8	15	7	13	15	14	0.400
High School/Post-High School Trade/Technical School	16	30	24	46	40	38	
1 to 3 Years of College	10	19	7	13	17	16	
≥ 4 Years of College	19	36	14	27	33	31	
Place of Birth							
Korea	54	98	52	100	106	99	1.000
China	1	2	0	0	1	1	
Number of Years Living in the US (17 ±9, 1-39)*							
10 years or less	20	36	18	35	38	36	0.239
11 to 20 years	13	24	19	37	32	30	
21 years or more	22	40	14	27	36	34	
Language Use with Friends/Language Speak Most of the Time							
Only Korean	28	51	26	51	54	51	1.000
Mostly Korean	23	42	22	43	45	42	
Only, Mostly, Half in English	4	7	3	6	7	7	
Language in Which Read Newspapers or Magazines							
Only Korean	34	62	35	69	69	65	0.770
Mostly Korean	17	31	13	25	30	28	
Only, Mostly, Half in English	4	7	3	6	7	7	
Language in Which Watch Television Programs							
Only Korean	22	40	21	40	43	40	0.702
Mostly Korean	19	35	21	40	40	37	
Only, Mostly, Half in English	14	25	10	19	24	22	
Consider Yourself More Korean vs. More American							
More Korean	47	87	44	86	91	87	0.909
Equal Blend of Both or More American	7	13	7	14	14	13	
Have Medical Insurance							
Yes	9	16	8	15	17	16	0.856
No	46	84	45	85	91	84	

a. X<sup>2</sup> or Fisher's Exact Test

 $<sup>^{\</sup>star}$  (mean  $\pm$  standard deviation, range) in total sample, no differences between groups Note: Frequencies do not always sum to total sample due to missing responses

Table 2. Health Related Characteristics by Study Group

	Intervention (n=58)		Control (n=58)		Total (n=116)		
	n	%	n	%	n	%	p-value <sup>a</sup>
Health Status							
Poor	14	25	9	17	23	21	0.285
Fair	27	49	22	41	49	45	
Good	10	18	16	30	26	24	
Very Good/Excellent	4	7	7	13	11	10	
Have Family History of Cancer	19	37	25	47	44	42	0.270
Type of Abnormality							
Abnormal mammogram	34	76	31	78	65	76	0.833
Other	11	24	9	23	20	24	
Type of Follow-up Test Needed							
Diagnostic Mammogram and/or Ultrasound	44	79	38	76	82	77	0.786
Diagnostic Mammogram 6-month Follow-up	10	18	11	22	21	20	
Other (Ultrasound Guided Code Biopsy, Repeat Mammogram, Repeat CBE)	2	4	1	2	3	3	
Comfort Discussing Health Care With Physician							
Very Comfortable	17	33	14	28	31	31	0.623
Somewhat Comfortable	32	63	32	64	64	63	
Not Comfortable at All	2	4	4	8	6	6	
Worry About Future Health When Doctor Recommended Exam							
Very Much Worried	9	16	5	10	14	13	0.699
Quite a Bit Worried	15	27	14	27	29	27	
A Little Worried	26	47	26	50	52	<b>4</b> 9	
Not at All Worried	5	9	7	13	12	11	

a. X<sup>2</sup> Test

Note: Frequencies do not necessarily sum to total sample due to missing responses

Table 3. Support and Barriers for Completing Follow-up Exam (Intervention Group Only) (n=58)

	7, \	
	<u> </u>	%
Reasons for Getting CBE/Mammogram		
Doctor Recommended	46	<i>7</i> 9
Get one every year	33	57
Family/Friends/TV Suggested It	24	41
Lump in Breast	22	38
Had Pain/Nipple Discharge	10	17
Experience During Last Clinic Visit		
Treated Politely During Last Visit	54	93
Had Problem Communicating with Doctor/Staff	43	74
Someone Answered Questions	38	66
Found it Difficult to Ask Questions of Doctor/Nurse	26	45
Had to Wait Too Long at Clinic	19	33
Factors Supporting Completion of Follow-up Exam		
Understand Recommended Exam	48	83
Have Someone to Talk/Get Help With Problems (Medical Problems)	45	78
Can Think of Ways to Work Out Problems	44	76
Able to Ask Relative/Friend/Neighbor to Accompany to Clinic	38	66
Able to Ask Relative/Friend/Neighbor Care For Child/Elder During Appointment	32	<i>5</i> 5
Have a Regular Doctor For Medical Exams	12	21
Worries and Concerns		
Questions/Worries About Cost of Exam	54	93
Worried About Finding Serious Problem From Exam	43	74
Worried About Recommended Exam or Possible Treatment	40	69
Sometimes Forget About Medical Appointments	18	31
Have Trouble Scheduling Follow-up Exam	17	29
Did Not Get Follow-up Exam b/c Feel They Don't Need It	10	17
Trouble Getting Transportation to Clinic	8	14
Needs		
Would Like to Be Reminded About Appointment	45	<i>7</i> 8
Want More Information About Recommended Exam	14	24

Table 4. Self-reported Completion of Follow-up Exam by Study Arm

	Intervention		Cont	rol	
Approach	n	%	n	%	p-value <sup>a</sup>
Study completers	56/58	97	39/58	67	<0.001
Intent-to-Treat Analysis					
Imputation of "no follow-up" for study non-completers	56/92	61	39/84	46	0.055
Imputation of "5% follow-up" for study non-completers	58/92	63	40/84	48	0.049
Imputation of "30% follow-up" for study non-completers	66/92	72	47/84	56	0.025
Imputation of "60% follow-up" for study non-completers	76/92	83	55/84	65	0.006

a. X<sup>2</sup> or Fisher's Exact Test

Figure 1. Study Flow Chart

